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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,332	07/23/2004	Marie Malissen	3665-113	9194

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/502,332	MALISSEN ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/23/04 (filing date)*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 35-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 35-64 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Preliminary Amendment, filed 7/23/04, has been entered. Claims 1-34 are cancelled; claims 35-64 are newly added.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 35, 36, 39-47, 57-60, drawn to a non-human animal having a mutated LAT gene, wherein the sequence of the mutant LAT protein corresponds to a wild-type sequence and contains a single mutation of the tyrosine corresponding to Y136 in the mouse LAT protein, cells isolated from the animal, a mouse gene encoding said mutant LAT protein.

Group II, claim(s) 35, 37, 39-41, 45-47, 61, drawn to a non-human animal having a mutated LAT gene, wherein the mutated LAT gene codes for a mutant LAT protein comprising exon 7 of SEQ ID NO: 2, cells isolated from the animal, a mouse gene encoding said mutant LAT protein.

Group III, claim(s) 35, 38, 39-41, 45-47, drawn to a non-human animal having a mutated LAT gene, wherein the sequence of the mutant LAT protein contains a composite mutation of the three distal tyrosine residues, cells isolated from the animal,

Group IV, claim(s) 48-50, drawn to methods of screening for drugs for treatment of allergy, asthma, and/or disease associated with TH2 cell deregulation *in vivo*.

Group V, claim(s) 51, drawn to methods of screening for drugs for treatment of allergy, asthma, and/or disease associated with TH2 cell deregulation *in vitro*.

Group VI, claim(s) 52, drawn to methods for screening drugs that regulate the activity of TH2 cells *in vivo*, utilizing a non-human animal comprising a mutated LAT gene.

Group VII, claim(s) 53, drawn to methods of producing a pharmaceutical composition for treating a disease associated with deregulated TH2 cell activity.

Group VIII, claim(s) 54, 55, 64, drawn to producing human IgE antibodies by providing a non-human animal expressing humanized IgE and mating it with an animal having a mutated LAT protein.

Group IX, claim(s) 56, drawn to a B cell hybridoma.

Group X, claim(s) 62, 63, drawn to diagnostic method and kit for asthma, allergy, eosinophilia and/or TH2 cells deregulation by detection of a mutated LAT gene coding for a mutant LAT protein containing a single mutation of the tyrosine Y132.

Group XI, claim(s) 62, 63, drawn to diagnostic method and kit for asthma, allergy, eosinophilia and/or TH2 cells deregulation by detection of a mutated LAT gene coding for a mutant LAT protein containing a composite mutation of three distal tyrosines Y171, Y191, and Y226.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of Invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product
2) A product and a process of use of said product
3) A product, a special process of manufacture of said product, and a process of use of said product
4) A process and an apparatus specially designed to carry out said process
5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant invention.

37 CFR 1.475 (c) states that:
"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:
"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) states:
"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

Groups I-XI lack the same or corresponding special technical feature, because a special technical feature is defined as one that defines a contribution over the prior art (see PCT Rule 13.2). The non-human mammal having a mutated LAT gene encoding for a mutant protein, wherein the mutant LAT protein leads to exaggerated TH2 cell differentiation fails to provide a contribution over the prior art, because mice have mutated LAT genes are known (See Sommers *et al.*, **J. Exp. Med**, 194(2): 135-142 (July 16, 2001)), where they teach mice which contain a mutation of the distal four tyrosines of LAT. Furthermore, LAT is known for its essential role in T cell development (Zhang *et al.* (**Immunity**, 10:323-332, March 1999). Thus, the non-human mammal first recited in the claims does not provide a contribution over the prior art, and thus, the claims as a whole lack unity. Groups I-III and IX are directed to different products (different mice containing different mutations and a B cell hybridoma), which are not required nor recited for the implementation of the other. Note above, that multiple products are do not have the same or corresponding special technical feature, do not provide unity of

invention. Groups IV-VIII and X-XI are directed to different methods that each have materially separate protocol and require specific consideration. Accordingly, it is determined the Groups I-XI fail to have unity of invention. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

thaian ton

Thaian N. Ton
Patent Examiner
Group 1632